REMARKS

In response to the rejections raised in the August 22, 2002 Office Action, our comments follow. Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 23-36 are pending in this application. Claims 23, 24, 33 and 34 have been amended; claims 35 and 36 have been added. Support for the amended claims is found throughout the specification. No new matter is added by this amendment.

In the Amendment filed on May 6, 2002, the claims were inadvertently amended to recite "rice", rather than the intended "*Brassica*". The herein amendments to claims 23 and 24 correct the scope of the claims to cover *Brassica* plants, cells and tissues. As such, claims 23-28, and 33-36 are within the scope of the elected invention, and it is requested that they all be considered in this application.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. DOUBLE PATENTING

Claims 33 and 34 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-5, 7-9 and 14-16 of co-pending application U.S.S.N. 09/430,497. The issue of whether there is indeed double patenting is contingent upon whether the claims of both applications are ultimately allowed; and, if so, whether the Examiner believes there is still overlap with claims in the cited application. If, upon agreement as to allowable subject matter, it is believed that there is still a double patenting issue, a Terminal Disclaimer will be filed at that time. Accordingly, holding the double patenting rejection in abeyance until agreement is reached as to allowable subject matter is requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH ARE OVERCOME

Claims 33 and 34 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

The Office Action alleged that claims 33 and 34 omit essential steps. These claims have been amended to mirror the language of claim 27 of U.S. Patent No. 6,468,747. It is assumed that since this claim issued on October 22, 2002, the language and structure conform with current U.S. practice.

The Office Action also objected to the recitation of "recognizes" with respect to the primer or probe. This language has been changed to "hybridizes", which is an accepted term in the art. Hybridization is discussed in the paragraph bridging pages 15 and 16 of the specification.

Claims 33 and 34 were also rejected based on the assertion that the metes and bounds of what constitute the flanking regions are not defined in the specification. To the contrary, the term "flanking region" is clearly defined on page 12, lines 15-23, of the application. Furthermore, on pages 32-33 of the specification, the 5' flanking region in SEQ ID NO:8 and the 3' flanking region in SEQ ID NO:10 are identified. More specifically, it is stated that the sequence between nucleotides 1 and 234 of SEQ ID NO:8 corresponds to plant DNA. Thus, this is the flanking region (the region of the plant genome which is located immediately upstream and contiguous with the foreign DNA) within SEQ ID NO:8. Similarly, on page 33, the sequence between nucleotides 194 and 416 corresponds to the flanking sequence within SEQ ID NO:10.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, are requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH ARE OVERCOME

Claims 33 and 34 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement and adequate written description. The rejections are traversed and will be treated together.

In order to support the enablement rejection, the Examiner cites a number of references that relate to the unpredictability of the transfer of genes by crossing. The Examiner indicates that Reynaerts, Rong et al., Goring et al. and Eshed et al. suggest that the transmission of the genes by sexual crossing is not evident, and that even if such transmission is successful, phenotypic characteristics liked thereto are not necessarily maintained, meaning that the presence

of a molecular marker does not guarantee a phenotypic introgression. This argument is neither relevant nor correct.

The specification describes the introduction of elite event MS-B2 into *Brassica juncea, Brassica napus*, winter oilseed rape, and *Brassica rapa* by repeated backcrossing. Despite the fact that there are considerable differences between these species and varieties, adequate expression of the transgene, combined with optimal agronomic performance was observed. Page 28 of the application (under heading 2.3) describes how elite event MS-B2 was tested for its performance in different genetic backgrounds. Thus, it was also shown that elite event MS-B2 can be crossed into different *B. napus* cultivars. Moreover, this was one of the criteria for its selection as an elite event.

Applicants dispute the assertion on page 8 of the Office Action, that "the availability of MS-B2 designated lines of all *Brassica* species [is] essential to the practice of the claimed invention..." A similar issue is also raised on page 14 of the Office Action with respect to written description. The claims relate to the confirmation of seed purity by identifying the presence (or absence) of an MS-B2 specific DNA sequence. This DNA sequence is identified using a method that identifies the flanking region, i.e. a specific sequence that is contiguous with the foreign DNA. Only the presence or absence of this specific DNA sequence in the genome of the seeds tested will determine the purity of the seedlot. Thus, the issue of whether or not the elite event MS-B2 can be crossed into all other species and varieties while maintaining its elite event characteristics is irrelevant to the invention as described in claims 33 and 34.

The citation of Knapp et al. is also not applicable to the claimed invention. Knapp et al. allegedly demonstrate that determination of the insertion site (or 5' and 3' flanking regions) of a T-DNA is unpredictable in the absence of genetic mapping of the insertion site. The goal of the present invention is to identify the presence or absence of the foreign DNA in the genome of plant material, specifically in a seedlot. This can be achieved using the methods of the invention. Where the foreign DNA is inserted into the genome, in terms of chromosome mapping, is irrelevant.

The Office Action goes on to refer to Knapp et al. and Thomas et al. to suggest that using a probe directed to a flanking sequence is not reliable. These references are not applicable to the instant invention. They relate to transposon-carrying T-DNAs, whereby plants comprising these T-DNAs are crossed with plants comprising the transposon activator (Ac). These are specific

sequences used to transpose the transposon-carrying T-DNA sequences to different sites in the genome, and thus yield very different patterns when analyzed in Southern blots. Furthermore, it should be noted that the probe used in Figure 3 of Knapp et al., cited by the Examiner, is indicated as fragment "B" of Figure 1, which is clearly an internal fragment of the T-DNA, and not, as the Examiner suggests, "a DNA probe specific to a region of plant genomic DNA flanking the T-DNA insertion site".

Knapp et al. and Thomas et al. relate to a system that is used specifically to create a variety of insertion sites of a specific T-DNA. In the present invention, a T-DNA is inserted in one location in the genome, as a result of transformation, and is stable inherited. (See Example 3.3 on page 33, lines 9-15 of the specification.) Thus, the identification of this stable insertion in no way relates to the description of the different insertions purposely obtained by the transposon technology referred to in the Office Action.

On page 10 of the Office Action, the Examiner alleges that the application "fails to provide guidance for any particular procedure for utilizing or making any specific probe, or any specific chemical or environmental condition for its use in the recited method, that would be essential to make and use the claimed invention." The Examples are replete with procedures for using the specific primers and probes (identified in the application by SEQ ID NO, for example SEQ ID NOs:11 and 12) to identify plants containing elite event MS-B2 (see Example 5 in particular).

The Office Action further asserts that the specification does not contain support for a broadly claimed trait of male sterility in *Brassica* grown under all growth conditions. This is also irrelevant and incorrect. The plants comprising elite event MS-B2 were, in fact, tested for plant phenotype and agronomic performance under different conditions, and were selected based thereon, as is detailed in the specification on page 27, lines 3-9. Nevertheless, this is irrelevant with respect to claims 33 and 34, which relate to a method for confirming seed purity based on the presence of a specific DNA in the genome of the seeds tested.

The Office Action goes on to assert, on page 11, that "the metes and bounds of the *B. napus* and PTA29-barnase-comprising genomic introgression of any *B. napus* genome into *B. juncea* genome" are not disclosed. To the contrary, the specification clearly defines elite event MS-B2 in terms of a specific genomic characterization. Elite event MS-B2 comprises the transgene comprising TA29-barnase and PNOS-barstar in a specific location in the *Brassica*

genome, and can be identified using molecular techniques that will identify only those plants having the transgene at that specific location. More specifically, this is accomplished using the MS-B2 elite event PCR identification protocol detailed on pages 36-40 of the application. All plants comprising elite event MS-B2 will be identified using this method. Thus, the MS-B2 carrying plants or plant material are clearly defined. Based thereon, methods can be developed to identify the presence of the event in seedlots using probes hybridizing to the flanking regions of the event. The functional limitation of the claims is that the method should identify MS-B2, which is characterized in the specification. It is therefore submitted that the metes and bounds of the invention would be clear to the skilled artisan.

The claims have been amended to more clearly define the steps involved in the claimed methods, which should clear up any questions, as raised on page 13, regarding "confirming seed purity". Further, as discussed above, the hybridization steps and reaction conditions are defined in the specification. The word "recognizes", objected to on page 13 of the Office Action, has been changed to "hybridizes with".

The Office Action further states that the plants of the invention must be available to the public. With respect to the biological materials, the undersigned states that she is a registered patent attorney representing the Applicants, that the biological materials, accession no. PTA-850 and PTA-2485, identified in the application as deposited, were deposited under the terms of the Budapest Treaty with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland, 20852, USA, and that:

(a) during the pendency of this application, access to each of the Deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon availability of the each of the Deposits to the public will be irrevocably removed upon granting of the patent;

(c) each of the Deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of each of the Deposits was made; and

(e) each of the Deposits will be replaced if it should ever become inviable.

V. THE REJECTION UNDER 35 U.S.C. §103 IS OVERCOME

Claims 33 and 34 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Mariani et al. The rejection is traversed. Mariani et al. describe the insertion of TA29-barnase into *Brassica napus*, however, as discussed above, the gene is not inserted into a specific location in the genome, nor are the RFLP assays designed to detect whether the gene was inserted at the specific location. In the instant invention, the MS-B2 elite event PCR identification protocol is used to determine the presence or absence of the TA29-barnase and PNOS-barstar in plants or plant material, specifically seedlots. It would not be obvious or even possible to use the methods of Mariani et al. to arrive at the current invention, nor is there any teaching or suggestion in Mariani et al. to do so. Therefore, reconsideration and withdrawal of the §103 rejection is solicited.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

23. (Twice Amended) A method for identifying elite event MS-B2 in a transgenic *Brassica*[rice] plant, or cell or tissue thereof, or trangenic *Brassica*[rice] plant material, which method comprises detection of a MS-B2 specific region with a specific primer or probe which specifically recognizes the 5' flanking region in SEQ ID No. 8 or the 3' flanking region in SEQ ID No. 10 of MS-B2.

24. (Twice Amended) The method of claim 23, said method comprising amplifying a DNA fragment of between 160 and 200 bp from a nucleic acid present in said transgenic *Brassica*[rice] plant, or cell or tissue thereof, or trangenic *Brassica*[rice] plant material, using a polymerase chain reaction with at least two primers, one of which recognizes the 5' flanking region in SEQ ID No. 8 or 3' flanking region in SEQ ID No. 10 of MS-B2, the other which recognizes a sequence within the foreign DNA.

33. (Amended) A method for confirming seed purity, which method comprises detecting[detection of] an MS-B2 specific region comprising the insertion site of MS-B2 with a specific primer or probe which specifically hybridizes to[recognizes] the 5' flanking region of SEQ ID No. 8 or the 3' flanking region of SEQ ID No. 10 of MS-B2, and thus confirming seed purity if the MS-B2 specific DNA is so detected in seed samples.

34. (Amended) A method for screening seeds for the presence of MS-B2, which method comprises detecting[detection of] an MS-B2 specific region comprising the insertion site of MS-B2 with a specific primer or probe which specifically hybridizes to[recognizes] the 5' flanking region of SEQ ID No. 8 or the 3' flanking region of SEQ ID No. 10 of MS-B2, and thus confirming the presence of MS-B2 if the MS-B2 specific DNA sequence is so detected in samples of seed lots.